



UNITED STATES DEPARTMENT OF COMMERCE  
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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/182,621	01/13/94	ENGELHARDT	D ENZ52
		18N1/1031	FEES, D EXAMINER
			ART UNIT PAPER NUMBER
			1807 9
			DATE MAILED: 10/31/95

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

Restriction only  
 This application has been examined  Responsive to communication filed on 12/22/94  This action is made final.

A shortened statutory period for response to this action is set to expire 1 month(s), 0 days from the date of this letter.  
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C.133.

**Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:**

1.  Notice of References Cited by Examiner, PTO-892.
2.  Notice of Draftsman's Patent Drawing Review, PTO-848.
3.  Notice of Art Cited by Applicant, PTO-1449.
4.  Notice of Informal Patent Application, PTO-152.
5.  Information on How to Effect Drawing Changes, PTO-1474.
6.

**Part II SUMMARY OF ACTION**

1.  Claims 1 - 90 are pending in the application.  
Of the above, claims \_\_\_\_\_ are withdrawn from consideration.
2.  Claims \_\_\_\_\_ have been cancelled.
3.  Claims \_\_\_\_\_ are allowed.
4.  Claims \_\_\_\_\_ are rejected.
5.  Claims \_\_\_\_\_ are objected to.
6.  Claims 1 - 90 are subject to restriction or election requirement.
7.  This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8.  Formal drawings are required in response to this Office action.
9.  The corrected or substitute drawings have been received on \_\_\_\_\_. Under 37 C.F.R. 1.84 these drawings are  acceptable;  not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-848).
10.  The proposed additional or substitute sheet(s) of drawings, filed on \_\_\_\_\_, has (have) been  approved by the examiner;  disapproved by the examiner (see explanation).
11.  The proposed drawing correction, filed \_\_\_\_\_, has been  approved;  disapproved (see explanation).
12.  Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has  been received  not been received  been filed in parent application, serial no. \_\_\_\_\_; filed on \_\_\_\_\_.
13.  Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1835 C.D. 11; 453 O.G. 213.
14.  Other

**EXAMINER'S ACTION**

**Part III DETAILED ACTION**

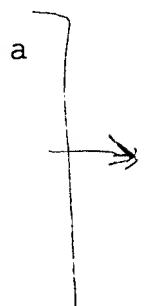
***Election/Restriction***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-51 and 73-80, drawn to an in vitro process for producing more than one copy of a nucleic acid , classified in Class 435, subclass 91.2.

Group II. Claims 52-72, drawn to a promoter-independent non-naturally occurring nucleic acid construct which when present in a cell produces a nucleic acid without the use of any gene product coded by said construct, and nucleic acid conjugates of this construct, classified in Class 435, subclass 320.1, for example.

Group III. Claims 81-90, drawn to a construct comprising a host promoter located on the construct such that the host transcribes a sequence in the construct coding for a different RNA polymerase, classified in Class 435, subclass 69.1 for example.



2. The inventions are distinct, each from the other because of the following reasons:

Inventions II, and III vs Invention I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the process may be practiced without the constructs of inventions II and III, using simply RNA primers for example. Further the products of invention II and III may be used respectively in different processes. The product of invention II may be used in processes that involve the controllable regulation of gene expression for the overproduction of proteins, while the product of invention III may be used in a method of purification of RNA polymerases.

Inventions II and III are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations. (M.P.E.P. § 806.05(c)). In the instant case, the combination as claimed does not require the

particulars of the subcombination as claimed because the construct of invention I does not require a nucleic acid sequence encoding a polymerase. The subcombination has separate utility such as overexpressing RNA polymerase for the purpose of purifying this protein.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. A telephone call was made to Enzo Therapeutics on Oct 26, 1995 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition

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under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

6. Papers related to this application may be submitted to Group 1800 by facsimile transmission via the P.T.O. Fax Center located in Crystal Mall 1. The CM1 Fax Center number is (703) 308-7939. Please note that the faxing of such papers must conform with the notice to Comply published in the Official Gazette, 1096 OG 30 (Nov 15, 1989).

An inquiry regarding this communication should be directed to examiner Dianne Rees, Ph.D., whose telephone number is (703) 308-6565. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1156.

Calls of a general nature may be directed to the Group receptionist who may be reached at (703) 308-0196.

Dianne Rees  
Dianne Rees  
Oct 27, 1995

  
W. GARY JONES  
SUPERVISORY PATENT EXAMINER  
GROUP 1800

10/30/95